II. Proposed Changes to the APC Groups and Relative Weights

Under the OPPS, we pay for hospital outpatient services on a rate per service basis that varies according to the APC group to which the service is assigned. Each APC weight represents the median hospital cost of the services included in that APC relative to the median hospital cost of the services included in APC 0601, Mid-Level Clinic Visits. As described in the April 7, 2000 final rule (65 FR 18484), the APC weights are scaled to APC 0601 because a mid-level clinic visit is one of the most frequently performed services in the outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review the components of the OPPS not less often than annually and to revise the groups and related payment adjustment factors to take into account changes in medical practice, changes in technology, and the addition of the new services, new cost data, and other relevant information. Section 1833(t)(9)(A) of the Act requires the Secretary, beginning in 2001, to consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights.

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median or mean cost item or service in the group is more than 2 times greater than the lowest median or mean cost item or service within the same group (referred to as the "2 times rule"). We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule "in unusual cases, such as low volume items and services."

The APC groups that we are proposing in this rule as the basis for payment in 2002 under the OPPS have been analyzed within this statutory framework.

A. Recommendations of the Advisory Panel on APC Groups

1. Establishment of the Advisory Panel

Section 1833(t)(9)(A) of the Act, which requires that we consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights, specifies that the panel will act in an advisory capacity. The expert panel, which is to be composed of representatives of providers, is to review and advise us

about the clinical integrity of the APC groups and their weights. The panel is not restricted to using our data and may use data collected or developed by organizations outside the Department in conducting its review.

On November 21, 2000, the Secretary signed the charter establishing an "Advisory Panel on APC Groups" (the Panel). The Panel is technical in nature and is governed by the provisions of the Federal Advisory Committee Act (FACA) as amended (Public Law 92-463). To establish the Panel, we solicited members in a notice published in the **Federal Register** on December 5, 2000 (65 FR 75943). We received applications from more than 115 individuals nominating either themselves or a colleague. After carefully reviewing the applications, CMS chose 15 highly qualified individuals to serve on the panel. The Panel was convened for the first time on February 27, February 28, and March 1, 2001. We published a notice in the **Federal Register** on February 12, 2001 (66 FR 9857) to announce the location and time of the Panel meeting, a list of agenda items, and that the meeting was open to the public. We also provided additional information through a press release and our website.

2. Specific Recommendations of the Advisory Panel and Our Responses

In this section of the proposed rule, we summarize the issues considered by the Panel, the Panel's APC recommendations, and our subsequent action with regard to the Panel's recommendations. The data used by the Panel in making its recommendation are the 1996 claims that were used to set the APC weights and payment rates for CY 2000 and 2001.

As discussed below, the Panel sometimes declined to recommend a change in an APC even though the APC violated the 2 times rule. In section II.C.3 of this preamble, we discuss our proposals regarding the 2 times rule based on the data we are using to recalibrate the 2002 APC relative weights (that is, claims for services furnished on or after July 1, 1999 and before July 1, 2000). That section also details the criteria we use in deciding to make an exception to the 2 times rule. We asked the Panel to review many of the exceptions we implemented in 2000 and 2001. The exceptions are referred to as "violations of the 2 times" rule in the following discussion.

APC 0016: Level V Debridement & Destruction

APC 0017: Level VI Debridement & Destruction

We asked the Panel to review the current placement of CPT code 56501, Destruction of lesion(s), vulva; simple, any method, in APC 0016 because the APC violates the 2 times rule. Because the procedure is a simple destruction of skin and superficial subcutaneous tissues, we would not expect it to have a median cost of $500. Thus, we believe that the higher costs associated with this code were the result of incorrect coding. To ensure that procedures in APC 0016 comply with the 2 times rule, we asked the Panel to consider one of the following clinical options:

- Move CPT code 56501 to APC 0017.
- Retain CPT code 56501 in APC 0016 but split APC 0016 into three APCs to distinguish simple destruction lesions from extensive destruction lesions.

The Panel rejected the option to split APC 0016 into three different APCs. The members stated that there was no validity in taking that approach because simple versus extensive destruction of lesions had greater significance in relation to physician work than in measuring facility resource use. They believed that many of the procedures

assigned to APC 0016 are performed in a procedure room rather than in the operating room. The Panel considered factors such as the use of anesthesia and the method used to destroy the lesions as indicators of differences in facility resource consumption between simple and extensive destruction of lesions. The Panel agreed that the simple destruction of lesions should be assigned to the same APC as the extensive destruction of lesions if a laser is used to remove simple lesions. In this case, the Panel stated that the similarity in resource use is based on the method or technique used to perform the procedure.

The Panel also noted that CPT code 11042, Debridement; skin, subcutaneous tissue, and muscle, is the most frequently performed procedure in APC 0016, accounting for approximately 85 percent of this APC's total volume. The Panel noted that this code had probably been billed incorrectly because of widespread misunderstanding about its definition.

The Panel also reviewed procedures assigned to APCs 0014 (Level III Debridement & Destruction) and 0015 (Level IV Debridement & Destruction) and compared similarities and differences among those procedures and the ones assigned to

APCs 0016 and 0017. During this comparative review, the Panel compared CPT code 56501 to the following two CPT codes: 46917, Destruction of lesion(s), anus, simple; laser surgery, which is assigned to APC 0014, and 54055, Destruction of lesion(s), penis, simple; electrodesiccation, which is assigned to APC 0016. In reviewing these three procedures, the Panel questioned whether the resources involved supported their current APC assignments. After considerable discussion, the Panel recommended the following:

- Move CPT code 56501 from APC 0016 to APC 0017.
- Move CPT code 46917 from APC 0014 to APC 0017.

The Panel recommended these changes to achieve clinical coherence and resource similarity among the procedures assigned to these APCs. Because CPT code 46917 is performed using laser equipment and requires anesthesia, the Panel believed it appropriate to move this procedure to APC 0017. Although the Panel considered the reassignment of CPT code 54055 to APC 0017, it did not recommend this change. The Panel's recommended changes would group in APC 0017 simple destruction of lesion procedures that use laser

or surgical techniques with extensive destruction of lesion procedures.

We propose to accept the Panel's recommendation regarding CPT code 56501 and to revise the APC accordingly. However, as shown below in Table 3, we are proposing to make additional changes to these APCs because of the 2 times rule.

APC 0024: Level I Skin Repair

APC 0025: Level II Skin Repair

APC 0026: Level III Skin Repair

APC 0027: Level IV Skin Repair

The composition of procedures in APCs 0025 and 0027 results in these APCs violating the 2 times rule. Therefore, we requested the Panel's advice in exploring other clinical options for reconfiguring the four skin repair APCs to achieve clinical and resource homogeneity among the procedures assigned to APCs 0025 and 0027 while retaining clinical and resource homogeneity for APCs 0024 and 0026. We asked the Panel to consider the following clinical options to achieve this result:

• Rearrange the procedures assigned to APCs 0024 through 0027 based on the size or the length of the skin incision.

• Rearrange the procedures assigned to APCs 0024 through 0027 based on the complexity of the repair, such as distinguishing repairs that involve layers of skin, flaps, or grafts from those that do not.

The Panel reviewed the various options presented, which were modeled based on the 1996 claims data used in constructing the current APC groups and payment rates. Using these data, the Panel discussed size and complexity of the various repairs, considered the clinical differences in performing the repairs on different anatomical sites, and the clinical differences involved in making skin repairs using flaps and grafts versus layers of skin. As a result of its review, the Panel stated that they found no compelling clinical advantages in the options presented. The Panel also agreed that more current data would be needed to make appropriate recommendations about the actual merits and benefits of the various options. For these reasons, the Panel recommended the following:

• Make no changes to APCs 0024 and 0027.

• Reevaluate these APCs with new data when the Panel meets in 2002.

• The Panel, in preparation for the 2002 meeting, will discuss with and gather clinical and utilization information from their respective hospitals regarding these procedures.

We propose to accept the Panel's recommendations. However, as shown in Table 3, we are proposing to make changes to these APCs based on the use of new data and application of the 2 times rule.

APC 0058: Level I Strapping and Casting Application

APC 0059: Level II Strapping and Casting Application

APC 0058 (which consists of the simpler casting, splinting, and strapping procedures) violates the 2 times rule. The median costs for high volume procedures in APC 0058 vary widely, ranging from $27 to $83. The median costs associated with presumably more resource-intensive procedures in APC 0059 are fairly uniform, ranging from $69 to $119. To limit the cost variation in APC 0058, we asked the Panel to consider the following options:

• Move the following four codes from APC 0058 to APC 0059: CPT code 29515, Application of short splint

(calf to foot); CPT code 29520, Strapping; hip; CPT code 29530, Strapping; knee; and CPT code 29590, Denis-Brown splint strapping.

- Create a new APC to include a third level of strapping and casting application procedures by regrouping all procedures assigned to both APCs 0058 and 0059 based on the following clinical distinctions: removal/revision, strapping/splinting, and casting.
- Package certain CPT codes assigned to APC 0058 with relevant procedures.

The Panel discussion revealed that codes grouped in APC 0058 are not always appropriately billed by hospitals. The Panel pointed out that code descriptors such as "strapping of the hip" are not commonly understood by hospital staff. The Panel noted that before implementation of OPPS, hospitals billed the items described by these codes as supplies (without a CPT code) when they were billed as anything other than an emergency room visit. They also stated that the use of these codes has been confused with the use of some codes associated with durable medical equipment. For these reasons, the Panel believed that the procedure costs reflected in our data are skewed.

As a result, the Panel recommended that we do the following:

- Make no changes to APC 0058.
- Provide appropriate education and guidance to hospitals regarding appropriate use and billing of codes in APC 0058.
- Resubmit APC 0058 to the Panel for reevaluation when later data are available.

We propose to accept the Panel's recommendations except that we propose to move CPT code 29515 to APC 0059 due to the 2 times rule and the newer data we are using for this proposed rule.

APC 0079: Ventilation Initiation and Management

The codes in APC 0079 represent respiratory treatment and support provided in the outpatient setting. The cost variation among the assigned procedures in this APC raises concern about hospital coding practices. The median costs for these procedures range from $40 to $315. We asked the Panel to clarify whether these procedures are performed on outpatients or if they are performed on patients who come to the emergency room and are later admitted to the hospital as inpatients.

The Panel acknowledged that there are major problems associated with appropriately assigning codes to these procedures which results in incorrect billing. The Panel concluded that additional information is necessary to better understand the issues raised. The Panel also advised that CPT code 94660, Continuous positive airway pressure ventilation (CPAP), initiation and management, is a sleep apnea procedure used in the treatment of obesity and is clinically different from all other procedures in APC 0079. For these reasons, the Panel recommended the following:

- Remove CPT code 94660 from APC 0079 and create a new APC for this one procedure.

We propose to accept the Panel's recommendation by creating a new APC 0065, CPAP Initiation.

APC 0094: Resuscitation and Cardioversion

We requested the Panel's assistance in determining whether it is clinically appropriate to remove the cardioversion procedures from APC 0094 because the rest of the procedures assigned to APC 0094 are emergency procedures rather than elective. We proposed that the Panel consider the creation of a new APC for the

cardioversion procedures or reassignment of the procedures to another APC that would be more appropriate in terms of clinical coherence and resource similarity. Splitting APC 0094 into two distinct groups, one for resuscitation procedures and the other for internal and external electrical cardioversion procedures, would not result in a significant difference in the APC payment rate for either of the new APCs.

The Panel considered whether it was clinically appropriate to combine internal and external cardioversion procedures (CPT codes 92960 and 92961, respectively) in the same APC. The Panel also questioned the conditions under which internal cardioversion procedures would be performed on an outpatient basis.

The Panel recommended that the only action we should take is to move CPT code 92961, Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure), from APC 0094 to APC 0087, Cardiac Electrophysiology Recording/Mapping.

We propose to accept the APC Panel recommendation.

APC 0102: Electronic Analysis of Pacemakers/Other Devices

The neurologic procedures included in APC 0102 (CPT codes 95970 through 95975), are significantly more complex than the routine cardiac pacemaker programming codes also assigned to this APC. Because we believe these codes are clinically different, we asked the Panel to consider the following:

- Create a new APC for the neurologic codes.
- Move the neurologic codes to APC 0215, Level I Nerve and Muscle Tests.

One presenter appearing before the Panel stated that APC 0102 involves clinical functions related to four different categories of devices; that is, pacemakers, defibrillators, infusion pumps, and neurostimulators. The presenter, who represented a device manufacturers' association, contended that these four categories of devices differ clinically. The presenter also stated that patients receiving these devices are clinically different and are even treated by different hospital departments. The presenter recommended the following:

- Split APC 0102 into two APCs: one APC for electronic analysis of pacemakers and other cardiac devices

and a separate APC for electronic analysis of infusion pumps and neurostimulators.

• The APC created for electronic analysis of infusion pumps and neurostimulators would include the following CPT codes:

Code	Descriptor
62367	Analyze spine infusion pump
62368	Analyze spine infusion pump
95970	Analyze neurostim, no prog
95971	Analyze neurostim, simple
95972	Analyze neurostim, complex
95973	Analyze neurostim, complex
95974	Cranial neurostim, complex
95975	Cranial neurostim, complex

• The APC created for electronic analysis of pacemakers and other cardiac devices would include the following CPT codes:

Code	Descriptor
93727	Analyze ilr system
93731	Analyze pacemaker system
93732	Analyze pacemaker system
93733	Telephone analy, pacemaker
93734	Analyze pacemaker system
93735	Analyze pacemaker system
93736	Telephone analy, pacemaker
93737	Analyze cardio/defibrillator
93738	Analyze cardio/defibrillator
93741	Analyze ht pace device sngl
93742	Analyze ht pace device single
93743	Analyze ht pace device dual
93744	Analyze ht pace device dual

The presenter stated that reorganizing APC 0102 as recommended would establish groups that are more clinically and resource similar than the current grouping. The presenter believes that APC 0102 as currently configured violates the 2 times rule. The median costs for the 21 procedures currently included in APC 0102 vary from $19 to $145. Other presenters clarified clinical aspects of the procedures, identified which practitioners perform them, the time it takes to perform them, and how they are to be billed. Yet another presenter speaking on behalf of a specialty society noted that the society had previously commented on this APC and requested that we remove CPT codes 93737 and 93738 from APC 0102.

The Panel noted that because most of the codes are new, having been established since 1996 (the base year of data available to the Panel), these newer procedures could not have been included in the data file used to create the current APC payment rates. In the absence of frequency and median cost data for many of these procedures, the Panel was concerned about reorganizing the codes in this APC. Nonetheless, the Panel recommended the following reorganization of APC 0102 to better reflect clinical

coherence:

• APC 0102 be split into four new APCs: one APC for analysis and programming of infusion pumps and CSF shunts; a second for analysis and programming of neurostimulators; a third for analysis and programming of pacemakers and internal loop recorders; and a fourth for analysis and programming of cardioverter-defibrillators.

We propose to accept the Panel's recommendations and propose to create four new APCs as follows:

APC 0689: Electronic Analysis of Cardioverter-Defibrillator

APC 0690: Electronic Analysis of Pacemakers and Other Cardiac Devices

APC 0691: Electronic Analysis of Programmable Shunts/Pumps

APC 0692: Electronic Analysis of Neurostimulator Pulse Generators.

APC 0110: Transfusion

APC 0111: Blood Product Exchange

APC 0112: Extracorporeal Photopheresis

The procedures included in APC 0110 are those related only to the services associated with performing the blood transfusion and monitoring the patient during the transfusion; the costs associated with the blood products

themselves are not included in APC 0110. We advised the Panel that we were not certain that cost data for blood transfusions excluded the costs of the blood products because the APC 0110 median cost of $289 seemed excessive. We expressed concern about hospital coding and billing practices for blood products, blood processing, storage, and transportation charges as represented in the 1996 data. We asked the Panel to advise us on how to clarify hospital billing and coding practices for blood transfusions; we also asked if the Panel members believe that the median costs for transfusion procedures include the costs for blood products and, if so, how the procedures should be adjusted to eliminate these costs.

A presenter representing a device manufacturers' association noted that these issues were examined extensively by several specialty societies that sent considerable data to us on the actual cost of the transfusion procedures before publication of the April 7, 2000 final rule (65 FR 18434). The presenter stated that the median costs for transfusion procedures that we used in calculating the final payment rate for APC 0110 was somewhat lower than the costs submitted by the

specialty societies. The presenter believes that our experience under the APC system is too limited for us to make a judgment concerning the validity of the median costs. The presenter also believes that the payment rate for APC 0110 should have been adjusted to include costs for blood safety tests, such as the hepatitis and HIV look-back tests mandated by the FDA over the past several years, because these costs were not included in the 1996 data used to construct the APC rates. The presenter stated that these tests are expensive and that they increase the hospitals' costs to provide the blood. However, it was unclear whether these tests are separately billable under the lab fee schedule.

In addition, the presenter explained that blood centers do not charge hospitals for blood because it is voluntarily donated, not manufactured. The presenter stated that blood centers charge hospitals what it costs them to provide the blood and that hospitals bill acquisition and processing charges rather than charges for the blood itself. Based on the information provided, the presenter urged the Panel not to revise APC 0110 until more data become available.

For APC 0111, another representative of a specialty society recommended that CPT code 36521, Therapeutic apheresis; with extracorporeal affinity column absorption and plasma reinfusion, be moved from APC 0111 to APC 0112. The presenter stated that CPT code 36521 is more similar clinically and in resource use to 36522, Photopheresis, extracorporeal which is in APC 0112. The presenter stated that a major difference between the procedure represented by CPT codes 36521 and 36520, Therapeutic Apheresis; plasma and/or cell exchange, which is also assigned to APC 0111, and the other procedures codes assigned to APC 0111, is that hospitals can bill separately for blood products such as the plasma or albumin used in performing plasma exchange procedures. The presenter described CPT code 36521 as a "self-contained" procedure not requiring the use of albumin or plasma, because the patient's own blood is processed through a machine and returned to the patient. The presenter stated that the materials and equipment used to perform this procedure make it much more costly than the other procedures assigned to APC 0111. The presenter, citing cost data from two medical centers where CPT code 36521 is frequently performed, stated that the total cost

of the procedure, including the cost of the adsorption column, is approximately $2000. At this time, the commenter noted, only one of the adsorption columns (Prosorba) used for this procedure is eligible for transitional pass-through payments, which means that payments for this procedure, which are based upon the APC payment alone, are too low when one of the other columns is used and no additional pass-through payment is made. It was stated that the cost of many of the adsorption columns is over $1000 per column. The presenter concluded that moving CPT code 36521 from APC 0111 to APC 0112 would comply with the statutory requirements for clinical coherence and resource similarity among procedures in the same APC.

The Panel discussed various adsorption devices used in performing CPT code 36521, their eligibility for transitional pass-through payments, as well as the clinical and resource use difference between CPT codes 36520 and 36551. After considerable discussion, the Panel recommended the following:

- Take no action on APC 0110.

• Move CPT code 36521 from APC 0111 to APC 0112 to achieve clinical coherence and resource similarity with photopheresis procedures included in APC 0112. However, the Panel cautioned that the payment for APC 0112 captured the cost of the entire procedure including the cost of the adsorption column. For this reason, any additional payment for the adsorption column through the transitional pass-through payment mechanism would be a duplicate payment. Therefore, the panel asked that CMS address this problem when considering their recommendation.

We propose to accept the Panel's recommendations. We note that effective April 1, 2001, the Prosorba column is no longer eligible for a transitional pass-through payment (see PMA-01-40 issued on March 27, 2001).

APC 0116: Chemotherapy Administration by Other Technique Except Infusion

APC 0117: Chemotherapy Administration by Infusion Only

APC 0118: Chemotherapy Administration by Both Infusion and Other Technique

We had received several comments requesting that oral delivery of chemotherapy and delivery of chemotherapy by

infusion pumps and reservoirs be recognized for payment under the OPPS. We asked the Panel to examine this issue.

With regard to oral administration of chemotherapy, the Panel heard several presenters discuss the need for extensive beneficiary education prior to administration of oral anticancer agents. The Panel agreed that the beneficiaries actually self-administer the drug and that beneficiary education was appropriately billed as a clinic visit. The Panel stated that this would be true whether the education involved cancer chemotherapy, diabetes management, or congestive heart failure management. Therefore, the Panel recommended that no new codes be created to specifically recognize oral administration of chemotherapy.

With regard to recognizing chemotherapy administration through infusion pumps and ports, the Panel heard several presentations that this is becoming a common method of administering not only cancer chemotherapy but also for administering other types of pharmaceuticals. It was pointed out that because CPT codes 96520, Refilling and maintenance of portable pump, and 96530, Refilling and maintenance of implantable pump or reservoir, were excluded

from the OPPS it was impossible for hospitals to be paid when performing these services. After lengthy discussion, the Panel recommended that refilling and maintenance of pumps and reservoirs be assigned to an APC.

The Panel also discussed the current HCPCS Q codes for chemotherapy administration and concluded that these codes should continue to be recognized in the OPPS. In addition, the Panel discussed whether a new Q code should be developed for extended chemotherapy infusions.

In summary, the Panel recommended the following:

- Hospitals be allowed to bill for patient education under the appropriate clinic codes.
- CPT codes 96520 and 96530 be assigned to a new APC.
- The current HCPCS Level II Q codes for chemotherapy administration should continue to be used.
- There is no need to develop a new HCPCS code for "extended chemotherapy infusions."
- CMS should consider developing a new HCPCS code for flushing of ports and reservoirs.

We propose to accept all the Panel recommendations except for the recommendation regarding flushing of ports and reservoirs. Flushing is performed in conjunction with

either a chemotherapy administration service or an outpatient clinic visit. In the first case, flushing is part of the chemotherapy administration and its costs are adequately captured in the costs of the chemotherapy administration code. In the second case, we believe that the costs of flushing are adequately captured in the costs of the clinic visit and need not be paid separately. We are proposing to create a new APC 0125, Refilling of Infusion Pump.

APC 0123: Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant

In APC 0123, the 1996 median cost for CPT code 38230, Bone marrow harvesting for transplantation, was only $15. We believe that this cost is lower than the actual cost of the procedure. Further, we do not have sufficient data to determine how often bone marrow and stem cell transplant procedures are performed on an outpatient basis. For these reasons, we requested the Panel's advice in clarifying the resources used in performing the procedures assigned to APC 0123, and the extent to which these procedures are performed on an outpatient basis.

The Panel noted that these transplant and stem cell harvesting procedures are being increasingly performed on an outpatient basis. One presenter representing a specialty society stated that 95 percent of these procedures are performed in the hospital outpatient setting. The presenter shared cost data from the bone marrow transplant unit of an academic medical center that showed the cost to harvest bone marrow to be about $1,800. The presenter observed that this cost is significantly higher than the APC payment rate of about $205 for APC 0123. Another presenter representing a group of hospitals stated that the supply costs alone for bone marrow harvesting are more than the current APC payment for the procedure. The presenter suggested that miscoding may have contributed to the low $15 median cost reflected in our database. After discussion, the Panel recommended the following:

- Make no changes in the procedures assigned to APC 0123 in the absence of sufficient data to support such modifications.

• The two presenters on this APC issue submit cost data for the Panel to use in reevaluating this issue at its 2002 meeting.

We note that our analysis of the more recent claims data we are using to reclassify and recalibrate the APCs in this proposed rule reveals a significant increase in costs for this APC resulting in a proposed payment rate that is double the current rate. However, very few procedures (fewer than 20) were billed on an outpatient basis. We will have the Panel review this APC again at their next meeting.

APC 0142: Small Intestine Endoscopy

APC 0143: Lower GI Endoscopy

APC 0145: Therapeutic Anoscopy

APC 0147: Level II Sigmoidoscopy

APC 0148: Level I Anal/Rectal Procedures

APC 0149: Level II Anal/Rectal Procedures

APC 0150: Level III Anal/Rectal Procedures

We presented these seven APCs to the Panel because of the inconsistencies in the median costs for some procedures included in APCs 0142, 0143, 0145, and 0147. We advised the Panel that our cost data do not show a progression of

median costs proportional to increases in clinical complexity as we would expect. For example, the data indicate that a therapeutic anoscopy assigned to APC 0145 costs more than twice as much as a flexible or rigid sigmoidoscopy assigned to APC 0147. We stated our concern that cost disparity could provide incentives to use inappropriate procedures. Because of these concerns, we asked the Panel's advice in determining whether one of the following actions should be taken:

- Divide the codes in APC 0142 into separate APCs representing ileoscopy and small intestine procedures.
- Combine diagnostic anoscopy and Level I sigmoidoscopy.
- Merge APCs 0143, 0145, and 0147 into one APC.

We also asked the Panel whether the costs associated with codes in APC 0145 appeared to be valid.

During the Panel discussion, it was noted that the data distributed to the Panel for these APCs indicated that most of the procedures are billed as single procedures only 50 percent of the time. This raised questions as to whether the data include procedures such as flexible sigmoidoscopies that were miscoded as rigid

sigmoidoscopies, colonoscopies, and anoscopies. In examining the data, the Panel considered what impact this miscoding would have on the cost data, and discussed the clinical approaches used to perform some of the procedures, what type of practitioners perform them, and other procedures and supplies that would be billed with them. As a result of this discussion, the Panel concluded that the data anomalies were probably attributable to miscoding because hospitals have not received sufficient guidance and information on appropriately coding procedures included in these APCs. The Panel also agreed that it would need more current data before it could consider reconfiguring these APCs. Therefore, the Panel recommended that we do the following:

- Make no changes to APCs 0142, 0143, 0145, and 0147.
- Provide information and guidance to better assist hospitals in understanding how to bill appropriately for services included in APCs 0142, 0143, 0145, and 0147.
- Resubmit these APCs to the Panel for review when newer data are available.

We propose to accept the Panel's recommendations.

APC 0151: Endoscopic Retrograde Cholangio-Pancreatography (ERCP)

We advised the Panel that we have received comments that indicate that it is inappropriate to assign both diagnostic and therapeutic ERCP procedures to the same APC. The commenters allege that virtually every hospital performs diagnostic ERCPs but only teaching hospitals perform therapeutic ERCPs. Based on our current data, if we created two APCs for ERCP procedures, the APC payment rate for therapeutic ERCPs would be lower than that for diagnostic ERCPs (approximately $526 and $535, respectively). Therefore, we requested the Panel's advice to help us determine whether to create separate APCs for diagnostic and therapeutic ERCP procedures.

A presenter speaking on behalf of a specialty society made the following points:

- ERCP is the most complex endoscopy procedure to perform and is usually performed by gastroenterologists.
- ERCP is usually performed at large hospitals.
- The most complex ERCP procedures are usually performed in teaching hospitals.

- Current payments for ERCP are lower than the costs to perform the procedure (based on cost and frequency data gathered from several teaching hospitals).

- Single claims should not be used to calculate an APC payment rate for ERCP services because a single ERCP procedure usually consists of several components, each with its own CPT code (e.g., sphincterotomy and stent placement). Therefore, an ERCP billed as a single CPT code would represent aberrant billing and would not accurately reflect the costs of an ERCP.

The OPPS data distributed to the Panel verified that the vast majority of the ERCP procedures are performed as multiple procedures. The Panel agreed that the use of single claims data could possibly skew the APC payment rate for ERCP services.

The Panel recommended that we do the following:

- Do not reconfigure the ERCP procedures in APC 0151.

- Resubmit this issue to the Panel for review when more recent data are available.

- Explore the feasibility of using multiple claims rather than single claims to calculate appropriate APC payment rates for ERCP procedures.

We propose to accept the Panel's recommendations. We are currently reviewing the potential for using multiple claims data for determining payment rates for ERCP procedures. As a first step in the process, in this proposed rule, we have determined a payment rate for ERCP procedures based on both single claims for ERCP procedures and, because ERCP procedures are typically done under radiologic guidance, on claims that included both an ERCP procedure and a radiologic supervision or guidance procedure in this APC. Using these additional claims has resulted in significantly increasing the number of claims used to determine the payment rate for this APC and in a much higher proposed payment rate (about $825).

APC 0160: Level I Cystourethroscopy and other Genitourinary Procedures

APC 0161: Level II Cystourethroscopy and other Genitourinary Procedures

APC 0162: Level III Cystourethroscopy and other Genitourinary Procedures

APC 0163: Level IV Cystourethroscopy and other Genitourinary Procedures

APC 0169: Lithotripsy

We advised the Panel that we had received a number of comments that advocated moving CPT code 52337, Cystoscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included), from APC 0162 to APC 0163. (We note that CPT code 52337 was deleted for 2001 and replaced with an identical CPT code, 52353. We will use the new code in the following discussion.) Because of these comments, we sought the Panel's advice in examining the clinical and resource distinctions between CPT code 52353 and other procedures assigned to APC 0162. Other information shared with the Panel noted that most of the procedures included in APC 0162 are complicated cystourethroscopies while those assigned to APC 0163 are largely prostate procedures.

One presenter representing a device manufacturer discussed the merits of reassigning CPT code 52353 to either APC 0163 or 0169 (APC 0169 contains a single CPT code, 50590, Lithotripsy, extracorporeal shock wave (ESWL)). The presenter was concerned that our decision to assign the cystourethroscopic procedure to APC 0162 rather

to APC 0163 was not explained in our April 7, 2000 final rule.

Furthermore, the presenter noted that this decision resulted in a 40 percent decline in payment for the procedure which will make it difficult for hospitals to provide this service because the capital equipment, probes, and fibers required to perform the procedure are expensive. Moreover, the probes and fibers are ineligible for transitional pass-through payments because they are not single-use items. At the Panel's request, the presenter discussed the clinical differences between CPT codes 52353 and 50590. The presenter stated that code 50590 is a noninvasive procedure that involves breaking up kidney stones using shock waves produced outside the patient while code 52353 is an invasive procedure that requires the urologist to insert different instruments through a cystoscope and a uretheroscope to access stones in the upper urinary tract (the ureter and kidney).

The presenter also compared the cost of performing CPT code 52353 with that for CPT code 52352, which involves the mechanical removal of stones. The presenter asked the

Panel to consider the following two options to resolve this issue:

- Reassign CPT code 52353 to APC 0169, Lithotripsy.

The presenter believes that this would be the most appropriate assignment clinically and from a cost perspective because both involve lithotripsy and require expensive capital equipment, fibers, and probes. Also, other payers using a similar procedure grouping system, ambulatory procedure groups (APGs), have grouped these procedures together.

- Restore CPT code 52353 to its original APC assignment, APC 0163.

In addition, the presenter expressed concern that the large number of procedures assigned to APC 0162 makes it difficult to achieve clinical homogeneity within the APC. The presenter asked that we work with appropriate groups to reconfigure APC 0162 because, as constituted, it appears to violate the 2 times rule.

The Panel had a lengthy discussion regarding whether to move CPT code 52353 to APC 0163 or to APC 0169. The Panel considered the resources used for procedures in APCs 0163 and 0169 and noted that the lithotriptor used for code

50590 may be purchased or leased and that lease rates for lithotriptors have frequently been inflated. Furthermore, it noted that much of the equipment and resource use required for code 52353 is similar to the resource use of other procedures in APC 0163. In spite of these considerations, the Panel voted eight to seven to recommend moving CPT code 52353 from APC 0162 to APC 0169 because both codes 52353 and 50590 are lithotripsy procedures.

We reviewed the panel discussion very carefully and noted the close vote. After careful consideration, we propose to disagree with the Panel's recommendation and move code 52353 to APC 0163. The 1999-2000 cost data, which contains over 400 single claims for code 52353 and over 6,000 single claims for code 50590, show that the median cost for code 52353 is much more similar to the median cost of other procedures in APC 0163 than it is to the median cost of APC 0169. Although both codes involve lithotripsy, the type of equipment used in the two procedures is very different. Clinically, the surgical approach used for code 52353 and the resources used (e.g., anesthesia and operating room costs) are much more similar to other procedures in APC 0163 than to those for code

50590. Additionally, the median cost for code 50590, which is $700 higher than that of code 52353, is dependent on the widely variable arrangements hospitals make for use of the extracorporeal lithotriptor. Therefore, we believe that placing code 52353 in APC 0163 maintains its clinical coherence and similar use of resources.

APC 0191: Level I Female Reproductive Procedures

APC 0192: Level II Female Reproductive Procedures

APC 0193: Level III Female Reproductive Procedures

APC 0194: Level IV Female Reproductive Procedures

APC 0195: Level V Female Reproductive Procedures

This group of APCs was presented to the Panel because APC 0195 violates the 2 times rule. To facilitate the Panel's review of this issue, we distributed cost data on all the female reproductive procedures assigned to these five APCs. These data showed that the median costs for procedures assigned to APC 0195 ranged from a low of $365 to a high of $1,817. The CPT code 57288, Sling operation for stress incontinence (e.g., fascia or synthetic), which is assigned to APC 0195, has the highest median cost of the procedures in this group. We discussed with the Panel two clinical options for rearranging the procedures assigned to

APC 0195 to comply with the 2 times rule. The first option would split APC 0195 into two separate APCs by separating vaginal procedures from abdominal procedures. The second option would split APC 0195 into three distinct APCs by retaining the separate APCs for abdominal and vaginal procedures and further distinguishing vaginal procedures based on whether they are simple or complex.

The Panel discussed the rapid increase in the rate at which CPT code 57288 is performed on an outpatient basis. The Panel stated that this procedure is becoming more routine and replacing many of the older, more complex urinary dysfunctional procedures. Questions were raised about the frequency with which this procedure is performed alone as opposed to being performed as one of several procedures. The Panel was advised that the sling material and the relevant anchors used in performing CPT code 57288 are eligible for transitional pass-through payments.

One presenter, speaking on behalf of a device manufacturer, supported our proposal to divide APC 0195 into different clinical groupings. The presenter's testimony was limited to a discussion of CPT code 57288. The presenter concurred with the Panel's assessment of the

current utilization trends for CPT code 57288, emphasized the high costs associated with performing this procedure, and highlighted the wide variation in techniques and devices used to perform it. Because of these factors, the presenter believes that the procedure is underpaid and that the 1996 cost data may not fully reflect the actual costs associated with performing CPT code 57288.

The Panel also closely reviewed the other four APCs for female reproductive procedures to ensure each was clinically homogeneous. As a result of this review, the Panel recommended a number of changes for these APCs. These recommendations and those for APC 0195 are as follows:

- Move CPT codes 56350, Hysteroscopy, diagnostic, and 58555, Hysterosocopy, diagnostic/separate procedure, from APC 0191 to APC 0194 (In 2001, CPT code 56350 was replaced with CPT code 58555.)

- Divide APC 0195 into two APCs to distinguish vaginal procedures from abdominal procedures.

- Retain the following vaginal procedures in APC 0195:

CPT Code	Descriptor
57555	Excision of cervical stump, vaginal approach: with anterior and/or posterior repair
58800	Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); vaginal approach
58820	Drainage of ovarian abscess; vaginal approach, open
57310	Closure of urethrovaginal fistula;
57320	Closure of vesicovaginal fistula; vaginal approach
57530	Trachelectomy (cervicectomy), amputation of cervix (separate procedure)
57291	Construction of artificial vagina; without graft
57220	Plastic operation on urethral sphincter, vaginal approach (e.g., Kelly urethral plication)
57550	Excision of cervical stump, vaginal approach
57556	Excision of cervical stump, vaginal approach; with repair of enterocele
57289	Pereyra procedure, including anterior colporrhapy
57300	Closure of rectovaginal fistula; vaginal or transanal approach
57284	Paravaginal defect repair (including repair of cystocele, stress urinary incontinence, and/or incomplete vaginal prolapse)
57265	Combined anteroposterior colporrhaphy; with enterocele repair
57268	Repair of enterocele vaginal approach (separate procedure)
56625	Vulvectomy simple; complete
58145	Myomectomy excision of fibroid tumor of uterus, single or multiple (separate procedure); vaginal approach
57260	Combined anteroposterior colporrhaphy;

57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
57250	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
56620	Vulvectomy simple; partial
57522	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; loop electrode excision

- Include the following abdominal procedures in a new APC titled "Level VI Female Reproductive Procedures."

CPT Code	Descriptor
58920	Wedge resection or bisection of ovary, unilateral or bilateral
58900	Biopsy of ovary, unilateral or bilateral (separate procedure)
58925	Ovarian cystectomy, unilateral or bilateral
57288	Sling operation for stress incontinence (e.g., fascia or synthetic)
57287	Removal or revision of sling for stress incontinence (e.g., fascia or synthetic)

- Move CPT code 57107 from APC 0194 to APC 0195, Level V Female Reproductive Procedures.

- Move CPT code 57109, Vaginectomy with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lympadenectomy and para-oortic lymph node

sampling (biopsy), from APC 0194 to the new APC, Level VI Female Reproductive Procedures.

We propose to accept all of these Panel recommendations. These APCs would be reconfigured and renumbered as APCs 0188 to 0194. We are also proposing to add new APCs for Level VII and Level VIII Female Reproductive Procedures (APCs 0195 and 0202, respectively) based on the 1999-2000 claims data and the 2 times rule.

APC 0210: Spinal Tap

APC 0211: Level I Nervous System Injections

APC 0212: Level II Nervous System Injections

The Panel heard testimony from two presenters regarding the merits of modifying these three APCs. The first presenter, speaking on behalf of a manufacturer, discussed CPT code 64614, Chemodenervation of muscles; extremities and/or trunk muscles (e.g., for dystonia, cerebral palsy, multiple sclerosis). The presenter advised the Panel that although this is a new code for 2001, the procedure is well established and formerly coded using CPT code 64640, Destruction by neurolytic agent; other peripheral nerve or branch. The new code was created to distinguish chemodenervation of limb and trunk muscles from

other chemodenervation procedures. The presenter claimed that this code is similar both clinically and in terms of resource use to the other chemodenervation procedures assigned to APC 0211, so it should be assigned to that APC instead of APC 0971, New Technology - Level II, where it is currently assigned.

The second presenter, representing a specialty society, proposed regrouping the procedures assigned to APCs 0210, 0211, and 0212 based on similar levels of complexity and median costs. The presenter's proposal also included reassignment to these APCs of interventional pain procedures currently assigned to APCs 040, Arthrocenteris and Ligament/Tendon Injection, 0105, Revision/Removal of Pacemakers, AICD, or Vascular Device, and 0971. The presenter contended that it was essential to reconfigure these APCs because of disparity in resource use among procedures currently assigned to the same APC. The presenter also claimed that many of these procedures are being underpaid in their current APC and, for that reason, a number of hospitals have chosen not to perform them in the outpatient setting. The presenter proposed establishing the following five levels of interventional

pain procedures by regrouping the procedures into new APCs as stated below:

- Level I Nerve Inujections (to include Trigger Point, Joint, Other Injections, and Lower Complexity Nerve Blocks):

CPT Code	Reassigned From APC
20550	040
20600	040
20605	040
20610	040
64612	0211
64613	0211
64614	0971
64400-64418	0211
64425	0211
64430	0211
64435	0211
64445	0211
64450	0211
64505	0211
64508	0211

- Level II Nerve Injections (to include Moderate Complexity Nerve Blocks and Epidurals):

CPT Code	Reassigned From APC
27096	0210
62270	0210
62272	0210
62273	0212
62310-62319	0212

- Level III Nerve Injections (to include Moderately High Complexity Epidurals, Facet Blocks, and Disk Injections):

CPT Code	Reassigned From APC
62280-62282	0212
62290	Currently Packaged
62291	Currently Packaged
64420-64421	0211
64470	0211
64472	0211
64475-64476	0211
64479	0211
64480	0211
64483-64484	0211
64510	0211
64520	0211
64530	0211
64630	0211
64640	0211

- Level IV Nerve Injections (to include High Complexity Lysis of Adhesions, Neurolytic Procedures, Removal of Implantable Pumps and Stimulators):

CPT Code	Reassigned From APC
62263	0212
64600	0211
64605	0211
64610	0211
64620	0211
64622-64623	0211
64626-64627	0211
64680	0211
62355	0105
62365	0105

- Level V Nerve Injections (to include Highest Complexity Disk and Spinal Endoscopies): CPT code 62287, Aspiration or decompression procedure, percutaneous, of nucleus pulposus of invertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous disketcomy, percutaneous laser diskectomy), reassigned from APC 0220, Level I Nerve Procedures.

The Panel recommended reassignment of CPT code 64614 from APC 0971 to APC 0211.

Concerning the suggested regrouping of interventional pain procedures, the Panel agreed that the recommended division of these procedures by clinical complexity would reflect resource use and was a reasonable approach to take. It was pointed out to the Panel that the costs for CPT codes 62290, Injection procedure for diskography, each

level; lumbar, and 62291, Injection procedure for diskography, each level; cervical or thoracic, were packaged into the procedures with which they were billed. Therefore, the Panel concurred with the regrouping of procedures to establish Levels I, II, III, and IV with the following exceptions:

- The Panel recommended that CPT codes 62290 and 62291 not be included in Level III because they are packaged injections and should not be unpackaged and paid separately.
- The Panel opposed moving CPT codes 62355, Removal of previously implanted intrathecal or epidural catheter, and 62365, Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion, from APC 0105 to Level IV Nerve Injections because they were neither clinically similar nor similar in resource use to the other codes assigned to this proposed APC.
- The Panel opposed the creation of Level V Nerve Tests as it included only one code and recommended that CPT code 62287 remain in APC 220.

We propose to accept the Panel's recommendations for these services. We propose to create new APCs 0203, 0204, 0206, and 0207 to accommodate these proposed changes.

APC 0215: Level I Nerve and Muscle Tests

APC 0216: Level II Nerve and Muscle Tests

APC 0217: Level III Nerve and Muscle Tests

We advised the Panel that we had received a comment contending that assignment of CPT code 95863, Needle electromyography, three extremities with or without related paraspinal areas, to APC 0216 created an inappropriate incentive to perform tests on three extremities rather than two or four extremities. The payment of about $144 for APC 0216 is greater than the payment of about $58 for the same tests when performed on one, two, or four extremities. This is due to the fact that CPT codes 95860, 95861, and 95864, Needle electromyography, one, two, and four extremities with or without related paraspinal areas, respectively, are assigned to APC 0215. We distributed data to the Panel that showed a median cost of about $141 for CPT code 95863, which is more than 3 times that of the median cost of $41 for CPT code 95864. We asked the Panel to consider the reassignment of CPT code 95863 from APC

0216 to APC 0215 and advised the Panel that, based on cost data available at the time of our meeting, this change could potentially reduce the payment for APC 0216. It was also noted that this change could result in a payment increase for APC 0215.

The Panel reviewed the cost data for APCs 0215 and 0216 and noted that the median costs for both CPT codes 95863 and 95864 appeared aberrant. Based on the information presented, the Panel recommended that we move CPT code 95863 from APC 0216 to APC 0215.

We propose to accept the Panel's recommendation with one exception. We are proposing to revise these APCs based on the 1999-2000 cost data and the 2 times rule, and CPT code 95863 would be assigned to a reconfigured APC for Level II Nerve and Muscle Tests (APC 0218).

APC 0237: Level III Posterior Segment Eye Procedures

We advised the Panel that procedures assigned to APC 0237 are high volume procedures and rank among the top outpatient procedures billed under Medicare. We have received a number of comments disagreeing with the assignment of CPT code 67027, Implantation of intravitreal drug delivery system (e.g., ganciclovoir implant), which

includes concomitant removal of vitreous, to APC 0237. This procedure was added to the CPT coding system after 1996 and, therefore, was not included in the 1996 data. We advised the Panel that ganciclovoir, the drug implanted during this procedure, is paid separately as a transitional pass-through item. Because the drug is paid separately, it should not be included in determining whether the resources associated with the surgical procedure are similar to the resources required to perform the other procedures assigned to APC 0237. We advised the Panel that, of the procedures assigned to APC 0237, we believe that CPT code 67027 is related to codes 65260, 65265, and 67005, all of which involve removal of foreign bodies and vitreous from the eye. To ensure that CPT code 67027 is assigned to the appropriate APC, we asked the Panel to consider creation of a new APC, Level IV Posterior Segment Eye Procedures, for CPT codes 65260, 65265, 67005, and 67027. Based on the APC rates effective January 1, 2001, the suggested change could lower the APC rate for the four procedures by $400.

The Panel reviewed the data and did not believe it was sufficient to support the creation of a new APC for these four procedures. Therefore, the Panel recommended that APC

0237 remain intact and that more recent claims data be analyzed to determine whether CPT code 67027 is similar to the other procedures assigned to APC 0237.

Based on the 1999-2000 claims data, we have determined that the resources used for code 67027 are similar to other procedures in APC 0237. However, we will present APCs 0235, 0236, and 0237 to the Panel at their next meeting to determine whether any further changes should be made. We are proposing to make various other changes to these APCs based on the new data and the 2 times rule.

APC 0251: Level I ENT Procedures

This APC violates the 2 times rule because it consists of a wide variety of minor ENT procedures, many of which are low volume services or codes for nonspecific procedures. In order to correct this problem, we proposed to the Panel that this APC be split by surgical site (e.g., nasal and oral). After reviewing cost data, the Panel agreed that the APC should be split but that current data were insufficient to determine how that split should be made. Therefore, the Panel asked that this APC, along with more recent cost data, be placed on the agenda at the next meeting.

We agree that this APC should be reviewed by the Panel at its next meeting. However, our review of the more recent cost data indicates that significant violations of the 2 times rule still exist. In order to correct this problem, but keep the APC as intact as possible, we propose to move CPT codes 30300, Remove foreign body, intranasal; office type procedure, 40804, Removal of embedded foreign body, vestiblue of mouth; simple, and 42809, Removal of foreign body from pharynx, to APC 0340, Minor Ancillary Procedures. This APC consists of procedures such as removal of earwax that require similar resources.

APC 0264: Level II Miscellaneous Radiology Procedures

We asked the panel to review this APC because it violated the 2 times rule and consisted of a wide variety of unrelated procedures. Specifically, we believe that the costs associated with CPT codes 74740, Hysterosalpingography, radiological supervision and interpretation, and 76102, Radiologic examination, complex motion (e.g., hypercycloidal) body section (e.g., mastoid polytomography), other than with urography; bilateral, were aberrant and that we would significantly underpay these procedures if we moved them into a lower paying APC. We

also asked the Panel to determine whether this APC and APC 0263, Level I Miscellaneous Radiology Procedures, should be reconfigured by body system. After considerable discussion, the Panel agreed that the procedures in these APCs were not clinically homogeneous; however, it recommended that we leave these APCs intact because the data do not support any more coherent reorganization. The Panel requested that this APC be placed on the agenda for the 2002 meeting.

We agree with the Panel with the following revisions. First, BIPA requires us to assign procedures requiring contrast into different APCs from procedures not requiring contrast. This required changes to a number of radiologic APCs including APCs 0263 and 0264. In addition, in this proposed rule, we would move CPT code 75940, Percutaneous Placement of IVC filter, radiologic supervision and interpretation, to a new APC 0187, Placement/Reposition Miscellaneous Catheters, because its costs were significantly higher than the costs of the procedures remaining in APC 0264.

APC 0269: Echocardiogram except Transesophageal

APC 0270: Transesophageal Echocardiogram

We asked the Panel to consider splitting these APCs based on whether or not 2D imaging is employed. After review of the data, the Panel recommended that we leave these APCs intact.

We propose to leave APC 0270 intact except for the addition of two new codes for transesophageal echocardiography. We also propose to split APC 0269 into two APCs, APC 0269, Level I Echocardiogram Except Transesophageal and APC 0697, Level II Echocardiogram Except Transesophageal. One APC (0697) would include comprehensive echocardiograms and the other APC (0269) would include limited/follow-up echocardiograms and doppler add-on procedures.

APC 0274: Myelography

We advised the Panel that APC 0274 is clinically homogeneous but that it violates the 2 times rule. Procedures assigned to this APC include radiological supervision and interpretation of diagnostic studies of central nervous system structures (e.g., spinal cord and spinal nerves) performed after injection of contrast

material. We shared data with the Panel that showed the median costs for the procedures assigned to this APC ranged from a low of about $109 to a high of about $295. We asked the Panel's recommendation for reconfiguring APC 0274 to comply with the 2 times rule.

We informed the Panel members that we packaged the costs associated with radiologic injection codes into the radiological supervision and interpretation codes with which they were reported. The reason for doing this is that hospitals incur expenses for providing both services and they typically perform both an injection and a supervision and interpretation procedure on the same patient. Therefore, since neither an injection code nor a supervision and interpretation code should be billed alone, it would not be appropriate for us to use single claims data to determine the costs of performing these procedures. However, we are using single claims data in order to accurately determine the costs of performing procedures. Therefore, in order to accurately determine the costs of a complete radiologic procedure, we had to package the costs of the injection component into the cost of the supervision and interpretation component with which it was billed.

The Panel believed that, in 1996, hospitals generally did not bill the injection code when performing myelography. Furthermore, in 1996, some hospitals kept patients overnight after a myelogram. More recently, postmyelogram recovery time has decreased to about 6 hours. For these reasons, the Panel believed that the median costs of $109 and $174 probably do not represent the actual resources used for CPT codes 70010, Myelography, posterior fossa, radiological supervision and interpretation, and 70015, Cisternography, positive contrast, radiological supervision and interpretation. Therefore, the Panel recommended the following:

- Make no changes to APC 0274.
- Review new cost data to determine whether payment would increase for APC 0274.

We propose to accept the Panel's recommendations.

APC 0279: Level I Diagnostic Angiography and Venography

APC 0280: Level II Diagnostic Angiography and Venography

We presented these codes to the Panel for several reasons. APC 0279 fails the 2 times rule, there are numerous codes in these APCs with no cost data, there are numerous "add on" codes in these APCs, and many of these

procedures were performed infrequently in the outpatient setting in 1996.

The Panel reviewed the clinical coherence of both APCs as well as the resources required to perform all these procedures. The Panel believed that it would be unusual for many of these procedures to be performed separately and that we would need to look at multiple claims to get accurate data. The Panel recommended the following:

- Create a new APC (APC 0287, Complex Venography) with the following CPT codes: 75831, 75840, 75842, 75860, 75870, 75872, and 75880.
- Move CPT codes 75960, 75961, 75964, 75968, 75970, 75978, 75992, and 75995 from APC 0279 to APC 0280.

We propose to accept the Panel's recommendations. We note that, as proposed, APC 0279 violates the 2 times rule because of the low cost data for CPT code 75660, Angiography, external carotid, unilateral selective, radiological supervision and interpretation. We believe that, for these procedures, these cost data are aberrant. This code is clinically similar to the other codes in APC 0279 and moving code 75660 to an APC with a lower weight

could be an inappropriate APC assignment. Therefore, we believe that an exception to the 2 times rule is warranted.

APC 0300: Level I Radiation Therapy

APC 0302: Level III Radiation Therapy

We presented this APC to the Panel because we received comments that the assignment of CPT code 61793, Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator), one or more sessions, to APC 0302 would result in inappropriate payment of this service. Many commenters wrote that stereotactic radiosurgery and intensity modulated radiation therapy (IMRT) required significantly more staff time, treatment time, and resources than other types of radiation therapy. Other commenters disagreed with our decision, effective January 1, 2001, to discontinue recognizing CPT code 61793, and to create two HCPCS level 2 codes, G0173, Stereotactic radiosurgery, complete course of therapy in one session, and G0174 Intensity modulated radiation therapy (IMRT) plan, per session, to report both stereotactic radiosurgery and IMRT.

We reported to the Panel that the APC assignment of these G codes and their payment rate was based on our

understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session, while IMRT was performed on an outpatient basis and required several sessions to deliver a complete course of treatment. We also explained to the Panel that it was our understanding that multiple CPT codes were billed for each session of stereotactic radiosurgery and IMRT. Therefore, we believed that the payment for APC 0302 was only a fraction of the total payment a hospital received for performing stereotactic radiosurgery or IMRT on an outpatient basis.

Radiosurgery equipment manufacturers, physician groups, and patient advocacy groups have both submitted comments to us and provided testimony to the APC Panel on these issues. These comments have convinced us that we did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services.

We are proposing to set forth a proposed new coding structure that more accurately reflects the clinical use of these services and the resources required to perform them. Our understanding of these services, based on review of the

comments, the testimony before the Panel, the Panel discussion and recommendations, and meetings with knowledgeable stakeholders, is described below.

Recent developments in the field of radiation oncology include the ability to deliver high doses of radiation to abnormal tissues (e.g., tumors) while minimizing delivery of radiation to adjacent normal tissues. Collectively, these procedures are called stereotactic radiosurgery and IMRT.

Clinically, there are essentially two services required to deliver stereotactic radiosurgery and IMRT. First, there is "treatment planning," which includes such activities as determining the location of all normal and abnormal tissues, determining the amount of radiation to be delivered to the abnormal tissue, determining the dose tolerances of normal tissues, and determining how to deliver the required dose to abnormal tissue while delivering a dose to adjacent normal tissues within their range of tolerance. These activities includes the ability to manufacture various treatment devices for protection of normal tissue as well as the ability to ensure that the plan will deliver the intended doses to normal and abnormal

tissue by simulating the treatment. Second, there is "treatment delivery," which is the actual delivery of radiation to the patient in accordance with the treatment plan. Treatment delivery includes such activities as adjusting the collimator (a device that filters the radiation beams), doing setup and verification images, treating one or more areas, and performing quality control.

Treatment planning requires specialized equipment including a duplicate of the actual equipment used to deliver the treatment, the ability to perform a CT scan, various disposable supplies, and involvement of various staff such as the physician, the physicist, the dosimetrist, and the radiation technologist. Treatment delivery requires specialized equipment to deliver the treatment and the involvement of the radiation technologist. The physician and physicist provide general oversight of this process.

Although there are several types of equipment, produced by several manufacturers, used to accomplish this treatment, it is the consensus of the commenters and the Panel that the most useful way to categorize stereotactic radiosurgery and IMRT is by the source of radiation used

for the treatment and not by the type of equipment used. One reason for this is that the clinical indications for stereotactic radiosurgery and IMRT overlap. Therefore, a single disease process can be treated by either modality but the cost of treatment varies by source of radiation used for the treatment. Second, while both stereotactic radiosurgery and IMRT can deliver a complete course of treatment in either one or multiple sessions, the cost of treatment delivery per session is relatively fixed, and is closely related to the source of radiation used for the treatment. Therefore, we believe that appropriate APC assignment and payment can be made by creating a small number of HCPCS codes to describe these services.

The proposed codes are as follows:

- GXXX1 Multi-source photon stereotactic radiosurgery (Cobalt 60 multi-source converging beams) plan, including dose volume histograms for target and critical structure tolerances, plan optimization performed for highly conformal distributions, plan positional accuracy and dose verification, all lesions treated, per course of treatment

- GXXX2 Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, per lesion
- G0174 Intensity modulated radiation therapy (IMRT) delivery to one or more treatment areas, multiple couch angles/fields/arcs custom collimated pencil-beams with treatment setup and verification images, complete course of therapy requiring more than one session, per session
- G0178 Intensity modulated radiation therapy (IMRT) plan, including dose volume histograms for target and critical structure partial tolerances, inverse plan optimization performed for highly conformal distributions, plan positional accuracy and dose verification, per course of treatment

We propose that HCPCS codes GXXX1, G0174, and G0178 have status indicators of S, while GXXX2 have a status indicator of T. We believe these are the correct status indicators because G0178 has a "per session" designation, while GXXX2 has a "per lesion" designation. Furthermore, it is our understanding that GXXX1 would not be billed on a "per lesion" basis as the planning process would take into account all lesions being treated and it would be extremely

difficult to determine resource utilization for planning on a "per lesion" basis. Because the costs of performing GXXX1 will vary based on the number of lesions treated, payment would reflect a weighted average.

It is our understanding that single-source photon stereotactic radiosurgery (or LINAC) planning and delivery are similar to IMRT planning and delivery in terms of clinical use and resource requirements. Therefore, we propose to require coding for single-source photon stereotactic radiosurgery under HCPCS codes G0174 and G0178.

Further, we are aware that the AMA is establishing codes for IMRT planning and treatment delivery for 2002 and we propose to retire G0174 and G0178 (with the usual 90-day phase out) and recognize the applicable CPT codes when they are established in January 2002.

We believe that all activities required to perform stereotactic radiosurgery and IMRT are included in the codes described above. In order to avoid confusion and to optimize tracking of these services in terms of both utilization and cost, we propose to discontinue the use of any other radiation therapy codes for activities involved

with planning and delivery of stereotactic radiosurgery and IMRT for purposes of hospital billing in OPPS. Thus, we would continue to not recognize CPT code 61793 for hospital billing purposes.

We believe the coding requirements set forth above not only simplify the reporting process for hospitals, but appropriately recognize the clinical practice and resource requirements for stereotactic radiosurgery and IMRT.

We seek comments on our proposal, including the code titles, descriptors, and coding requirements discussed above. We also request information regarding appropriate APC assignment and payment rates to inform our decision-making. In particular, we would like information regarding the costs of treatment delivery including any differences between the cost of a complete treatment in single versus multiple sessions.

We also note that several commenters requested placement of the stereotactic delivery codes in surgical APCs and we request clarification and support for these comments within the context of our coding proposal. Specifically, we are concerned that appropriate payment be made for GXXX2, which has a “per lesion” descriptor.

We believe that while the APC Panel did not make any specific recommendations regarding these codes, the concerns expressed by the Panel are addressed by our proposal.

APC 0311: Radiation Physics Services

APC 0312: Radio Element Application

APC 0313: Brachytherapy

We presented APC 0311 to the Panel because we believed our cost data for CPT codes 77336, Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy; 77370, Special medical radiation physics consultation; and 77399, Unlisted procedure, medical radiation physics, dosimetry, and treatment devices, and special services, were inaccurate. We were concerned that these procedures, particularly code 77370, were not being paid appropriately in APC 0311.

Presenters pointed out that, as with all radiation oncology services, the usual practice is to bill multiple CPT codes on the same date of service. Therefore, single

claims were likely to be inaccurate bills and did not represent the true costs of the procedure. For this reason, presenters believe that using single claims to set payment rates for radiation oncology procedures was inappropriate and that we needed to develop a methodology that allowed the use of multiple claims data to set payment rates for these services.

With regard to radiation physics consultation, presenters stated that the staff costs associated with CPT code 77370 were significantly greater than the costs of CPT codes 77336 and 77399. Therefore, they recommended that CPT codes 77336 and 77399 be moved from APC 0311 to APC 0304, Level I Therapeutic Radiation Treatment Preparation, and CPT code 77370 be moved from APC 0311 to APC 0305, Level II Therapeutic Radiation Treatment Preparation. The Panel agreed with this recommendation and we propose to accept the Panel's recommendation. We also agree that we should review the use of single claims to set payment rates for radiation oncology services. We plan to present this issue again at the 2002 Panel meeting.

We presented APCs 0312 and 0313 to the Panel because commenters were concerned that the payment rates were too

low for the procedures assigned to the APCs and that there were insufficient data to set payment rates for these APCs. The Panel agreed that the issue regarding the use of single claim data affected the payment rates for these services. However, there were insufficient data for the Panel to make any recommendations regarding these APCs. The Panel did request to look at the issue of radiation oncology at its 2002 meeting.

Therefore, we are proposing to make no changes to APCs 0312 and 0313 but will address radiation oncology issues at the Panel's 2002 meeting. We note that our updated claims data show very few single claims for procedures in these APCs. However, moving any of these procedures into other radiation oncology APCs would lower their payment rates.

APC 0371: Allergy Injections

We presented this APC to the Panel because it violates the 2 times rule. The median costs for CPT codes 95115, Professional Services for allergen immunotherapy not including provision of allergenic extracts; single injection, and 95117, Professional Services for allergen immunotherapy not including provision of allergenic

extracts; two or more injections, were lower than the median costs for the other services in this APC.

The Panel agreed that because codes 95115 and 95117 included administration of an injection only, the resource utilization for these services was lower than for the other services. The other services involve preparation of antigen and require more staff time and hospital resources to perform.

In order to create clinical and resource homogeneity, the Panel recommended that we create a new APC for codes 95115 and 95117 and that we leave the other services in APC 0371. We propose to accept the Panel recommendation and create a new APC 0353, Level II Allergy Injections, and revise the title of APC 0371 to Level I Allergy Injections.

Observation Services

See the discussion on observation services in section II.C.4 of this preamble for a summary of the Panel discussion and recommendations and our proposal.

Inpatient Procedure List

See the discussion of the inpatient procedures list in section II.C.5 of this preamble for a summary of the Panel discussion and recommendations and our proposal.